Discretionary Grants, 370 L'Enfant Promenade, SW., Aerospace Building, Washington, DC 20447–0002. Email: *OCS@lcgnet.com.* Telephone: 1–800–281–9519.

VIII. Other Information

Additional Information about this program and its purpose can be located on the following Web site: *http://www.acf.hhs.gov/programs/ocs*.

Dated: March 30, 2004.

Clarence H. Carter,

Director, Office of Community Services.

[FR Doc. 04–7609 Filed 4–2–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0132]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for premarket approval of medical devices.

DATES: Submit written or electronic comments on the collection of information by June 4, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Premarket Approval of Medical Devices—21 CFR Part 814 (OMB Control Number 0910–0231)—Extension

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth the requirements for premarket approval of certain class III medical devices. Class III devices are either preamendments devices that have been classified into class III, postamendments devices which are not substantially equivalent to a preamendments device, or transitional devices. Class III devices are devices such as implants, life sustaining or life supporting devices, or devices which otherwise present a potentially unreasonable risk of illness or injury, or are of substantial importance in preventing impairment of human health. Most premarket approval application (PMAs) are for postamendments class III devices.

Under section 515 of the act, an application must contain several pieces of information including full reports of all information concerning investigations showing whether the device is reasonably safe and effective. The application should also include a statement of components, ingredients, and properties and of the principle or principles of operation of such a device and should also include a full description of the methods used in, and the facilities and controls used for the manufacture and processing of the device; and labeling specimens.

The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a class III medical device and the criteria FDA employs in approving, denying, or withdrawing approval of a PMA and supplements to PMAs. The regulation's purpose is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for certain class III (premarket approval) medical devices. The regulations contained in part 814 facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the disapproval of PMAs and supplements to PMAs for devices that have not been shown to be reasonably safe and effective and that do not otherwise meet the statutory criteria for approval.

The Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105–115) was enacted on November 21, 1997, to implement revisions to the act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. Several provisions of this act affect the PMA process, such as section 515(d)(6) of the act. This section provided that PMA supplements were required for all device changes that affect safety and effectiveness of a device unless such changes are modifications to manufacturing procedures or method of manufacture. This type of manufacturing change requires a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

To make the PMA process more efficient, in the past 3 years FDA has done the following: Made changes to the PMA program based on comments received, complied with changes to the program mandated by FDAMA, and worked towards completion of its PMA reinvention efforts.

Respondents to this information collection are persons filing a PMA application or a PMA supplement with FDA for approval of certain class III medical devices. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. These respondents include entities meeting the definition of manufacturers such as manufacturers of commercial medical devices in distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments). Additionally, hospitals that reuse single use devices (SUDs) are also included in the definition of manufacturers. It is expected that FDA will receive four PMA applications from hospitals that remanufacture SUDs annually. This figure has been included in table 1 of this document, as part of the reporting burden in § 814.15.

The total estimated reporting and recordkeeping burden for this information collection is 113,464 hours. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/FDAMA Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.15, 814.20, and 814.37	64	1	64	837	53,568
814.39(f)	581	1	581	66	33,346
814.82	45	1	45	135	6,075
814.84	45	1	45	10	450
Section 201 (FDAMA)	10	1	10	10	100
Section 202 (FDAMA)	15	1	15	10	150
Section 205 (FDAMA)	8	1	8	50	400
Section 208 (FDAMA)	26	1	26	30	780
Section 209 (FDAMA)	8	1	8	40	320
Totals					95,189

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.82(a)(5) and (a)(6)	1,075	1	1,075	17	18,275
Totals					18,275

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The industry-wide burden estimate for PMAs is based on an FDA actual average fiscal year (FY) annual rate of receipt of 64 PMA original applications and 581 PMA supplements, using FY 1998 through 2002 data.

The burden data for PMAs is based on data provided by manufacturers by device type and cost element in an earlier study. The specific burden elements for which FDA has data are as follows:

- *Clinical investigations*: 67 percent of total burden estimate;
- *Submission of additional data or information to FDA during a PMA review*: 12 percent;
- *Additional device development cost (e.g., testing)*: 10 percent; and
- *PMA and PMA supplement preparation and submissions, and development of manufacturing and controls data*: 11 percent.

Paperwork Burden Estimate

The burden estimates were derived by consultation with FDA and industry personnel. FDA's estimates are based on actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals.

Reporting/Disclosure

The reporting burden can be broken out by certain sections of the PMA regulation as follows:

- § 814.15—*Research conducted outside the United States*
- § 814.20 —*Application*
- § 814.37—*PMA amendments and resubmitted PMAs*

The majority of the burden—53,568 burden hours—is due to the previously listed three requirements. Included in these three requirements are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates that 64 manufacturers (including hospital remanufacturers of single use devices) will be affected by these requirements based on actual average FDA receipt of new PMA applications in FY 1998 through 2002. FDA's estimate of the hours per response (837) was derived through FDA's experience and consultation with industry and trade associations. Included in these three requirements are the conduct of laboratory and clinical trails as well as the analysis, review, and physical preparation of the PMA application. In addition, FDA has based its estimate on the results of an earlier study that these requirements account for the bulk of the burden identified by manufacturers.

- § 814.39 (f)—*PMA supplements*: 33,346 burden hours

FDA believes that the amendments mandated by FDAMA for § 814.39(f), permitting the submission of the 30-day notices in lieu of regular PMA supplements, will result in an approximate 10 percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 33,346 hours of burden are needed to complete the requirements for regular PMA supplements.

- § 814.82—*Postapproval requirements*: 6,075 burden hours

Postapproval requirements concern approved PMAs that were not reclassified and require a periodic report. The range of PMAs that fit this category averaged approximately 45 per year (70 percent of the 64 periodic submissions). Most approved PMAs have been subject to some post approval

study requirement. Approximately half of the average submitted PMAs (32) require associated postapproval studies (i.e., followup of patients used in clinical trials to support the PMA or additional preclinical information) that is labor-intensive to compile and complete, and the other PMAs require minimal information. Based on experience and consultation with industry, FDA has estimated that preparation of reports and information required by this section require 6,075 hours (135 hours per respondent).

• § 814.84—*Reports*: 450 burden hours

Postapproval requirements described in § 814.82 require a periodic report. FDA has determined respondents meeting the criteria of § 814.84 will submit reports on a periodic basis. As stated previously, the range of PMAs fitting this category averaged approximately 45 per year. These reports have minimal information requirements. FDA estimates that respondents will construct their report and meet their requirements in approximately 10 hours. This estimate is based on FDA's experience and on consultation with industry. FDA estimates that the periodic reporting required by this section will take 450 hours.

Statutory Burden: The total hours for statutory burden is 1,750. This burden estimate was based on actual real FDA data tracked from January 1, 1998, to the present, and an estimate was derived to forecast future expectations with regard to this statutory data.

Recordkeeping

The recordkeeping burden in this section involves the maintenance of records used to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records would be required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMAs are eventually approved and 75 percent of those have original clinical trial data. Therefore, approximately 45 PMAs a year (64 annual submissions times 70 percent) would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of active PMA applications must maintain these records. PMAs have been required since 1976, and there are 1,075 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 1,075 holders of approved original PMAs, therefore, is 18,275 hours (1,075 approved PMAs with clinical data x 17 hours per PMA).

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

Dated: March 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7607 Filed 4–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0268]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Biological Products: Reporting of Biological Product Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Biological Products: Reporting of Biological Product Deviations in Manufacturing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 31, 2003 (68 FR 75572), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0458. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7608 Filed 4–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health; Office of the Director

Notice of Meeting

The Office of the Director, National Institutes of Health (NIH), announces a meeting of the NIH Blue Ribbon Panel on Conflict of Interest Policies, a working group of the Advisory Committee to the Director, NIH. The meeting is scheduled for April 5–6, 2004, beginning at 8:30 a.m. each day.

The meeting will be held at the NIH, 9000 Rockville Pike, Bethesda, Maryland, Building 31C, Conference Room 6. Attendance will be limited to space available. In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

On April 5, the Panel will be in public session from 10 a.m.–2 p.m.; the Panel will meet in closed, Executive Session, from 8:30–10 a.m. and from 2:15 p.m.–4 p.m. On April 6, the Panel will meet in closed, Executive Session, from 8:30 a.m.–2 p.m. Closed sessions will be used for the Panel to work on their recommendations and the report. The agenda will be posted on the NIH Web site (*http://www.nih.gov*) prior to the meeting. Any person wishing to make a presentation should notify Charlene French, Office of Science Policy, National Institutes of Health, Building 1, Room 103, Bethesda, Maryland 20892, telephone 301–496–2122 by April 2, 2004, or by e-mail: *blueribbonpanel@mail.nih.gov*.

Oral comments will be limited to 5 minutes. Due to time constraints, only one representative from each organization will be allotted time for oral testimony. The number of speakers and the time allotment may also be limited by the number of presentations.